

REMARKS

Claims 1, 2, 5-8 and 26-38 were examined. In the instant Final Office Action the Examiner has maintained the following rejections, which are set forth by number in the order they are addressed herein:

- 1) Claims 1, 2, 5, 6, 26-33, 35, 36 and 38 stand rejected under 35 USC § 112, first paragraph, as allegedly lacking enablement;
- 2) Claims 1 stand rejected under 35 USC § 112, second paragraph, as allegedly being indefinite; and
- 3) Claims 2-6 and 26-36 stand rejected under 35 USC § 102(a), as allegedly anticipated by Leonard et al., Arch Gen Psych, 59:1085-1096, 2002 (Leonard).

Applicants thank the Examiner for indicating that Claims 7, 8 and 37 are allowable. Even so, Applicants hereby amend Claims 1, 2, 8, 26 and 38, and cancel Claims 7 and 27-34, in order to further the prosecution of the present application and Applicants' business interests, yet without acquiescing to the Examiner's arguments. Applicants reserve the right to prosecute the original, similar, or broader claims in one or more future application(s). The amendments do not introduce new matter.

Applicants believe that U.S. Application No. 08/956,518, filed on October 23, 1997, provided support for multiple claims, such as original independent Claims 1, 9, 16 and 22. Nonetheless, during prosecution of the instant application, Applicants amended the claims to read upon methods for identifying individuals predisposed to schizophrenia, comprising detecting the presence of a polymorphism in the core promoter region of an $\alpha 7$ allele, wherein the polymorphism contributes to reduced transcription and/or comprises a -86 C to T substitution. Accordingly, Applicants hereby rescind their priority claim to U.S. Application No. 08/956,518, filed on October 23, 1997, and hereby amend the Specification by deletion of the priority claim. This is consistent with the Examiner's position that the claims "related to specific polymorphisms in the promoter region only merit the priority date of the instant application," which is November 26, 2003 (Office Action dated June 6, 2006, page 2). The Office's standard operating procedures permit cancellation of benefit claims in this manner. Specifically the Office teaches that as "a result of the 20-year patent term, it is expected, in certain

circumstances, that applicants may cancel their claim to priority by amending the specification or submitting a new application data sheet (no supplemental declaration is necessary) to delete any references to prior applications (MPEP 201.11 III G).

1) The Claims Are Enabled

The Examiner has rejected Claims 1, 2, 5, 6, 26-33, 35, 36 and 38 under 35 USC § 112, first paragraph, as allegedly lacking enablement. In particular the Examiner states

the specification, while being enabling for a method of identifying individuals with increased likelihood of having schizophrenia comprising providing a nucleic acid from a human subject, detecting the presence of a -86 C to T substitution in relation to the start codon of said alpha 7 allele beginning at residue 270 of SEQ ID NO:125, does not reasonably provide enablement for detecting the presence of at least one polymorphism within a core promoter region corresponding to SEQ ID NO:125 of said alpha 7 allele wherein said at least one polymorphism contributes to reduced transcription. Furthermore, the specification does not reasonably provide enablement for the use of any of the other variants as indicators that a human subject is predisposed to schizophrenia (Final Office Action, page 3).

Applicants respectfully disagree that the claims lack enablement.

Nonetheless Applicants hereby amend Claims 1, 2, 8, 26 and 38, and cancel Claims 7 and 27-34, in order to further the prosecution of the present application and Applicants' business interests, yet without acquiescing to the Examiner's arguments, and while reserving the right to prosecute the original, similar, or broader claims in one or more future application(s). In particular, Applicants have amended Claim 1 to recite "and d) providing a diagnosis of schizophrenia to said subject based on the presence of said at least one polymorphism and a physician interview." Support for the amendment of Claim 1 can be found for instance in Claim 7, now canceled. Specifically, elements of allowable Claim 7 have been imported into amended Claim 1, which should thereby cause Claim 1 to be allowable. In addition, Applicants have amended Claims 2 and 26 to recite "wherein said at least one polymorphism comprises a -86 C to T substitution in relation to a start codon of said α 7 allele beginning at residue 270 of SEQ ID NO:125." Lastly, Applicants have changed the dependency of Claims 8 and 38.

Thus, independent Claims 1 and 26 are now directed to the embodiments of previous Claims 7 and 34, which were not subject to the instant enablement rejection. As such Applicants

contend that the pending claims are enabled, and respectfully request that this rejection be withdrawn.

2) The Claims Are Definite

The Examiner has rejected Claim 1 under 35 USC § 112, second paragraph, as allegedly being indefinite. The Examiner indicates that there is some confusion construing the meaning of step b):

Does it mean that “said alpha-7 allele” comprises SEQ ID NO:125? Or does it mean detecting the presence of at least one polymorphism within a core promoter region of said alpha-7 allele corresponding to SEQ ID NO:125? (Final Office Action, page 7).

Applicants respectfully disagree that the claims are indefinite.

Nonetheless, Applicants have amended Claim 1 in order to further the prosecution of the present application and Applicants' business interests, yet without acquiescing to the Examiner's arguments, and while reserving the right to prosecute the original, similar, or broader claims in one or more future application(s). In particular Applicants have amended Claim 1 to recite “detecting the presence of at least one polymorphism within a core promoter region of said $\alpha 7$ allele, wherein said core promoter region corresponds to SEQ ID NO:125.” Support for this amendment can be found for example in Figure 12B showing the core promoter region for the CHRNA7 gene set forth as SEQ ID NO:125, with arrows depicting the locations of polymorphisms identified during development of the present invention.

As the pending claims are definite, Applicants respectfully request that this rejection be withdrawn.

3) Leonard Is Not Prior Art

The Examiner has rejected Claims 2-6 and 26-36 under 35 USC § 102(a), as allegedly anticipated by Leonard et al., Arch Gen Psych, 59:1085-1096, 2002 (Leonard). The Examiner states that

Applicant argues that Leonard et al. is not prior art and further indicates that the amendment of 12/11/06 is accompanied by a “Leonard declaration.” The Examiner notes that no such declaration is evident in the file. Moreover, there are

many authors on the publication of Leonard et al. and only two (Leonard and Freedman) are listed as inventors herein. ... It is suggested that applicant resubmit a Katz declaration to obviate the rejection (Final Office Action, page 8).

As suggested by the Examiner, Applicants hereby provide the Office with a Katz-type Declaration (attached at Tab 1) from inventors Leonard and Freedman. The new Katz-type Declaration is provided as evidence that the Leonard publication describes Applicants' work. Since Leonard is not prior art, Applicants respectfully submit that this reference does not anticipate (or make obvious) the pending claims.

CONCLUSION

Applicants believe the amendments and arguments set forth above traverse the Examiner's rejections and, therefore request that a timely Notice of Allowance be issued in this case. However, should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicants encourage the Examiner to call the undersigned collect.

Dated: January 28, 2008

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PATENT
Attorney Docket No.: VARD-07989

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Sherry Leonard *et al.*
Serial No.: 10/723,940 Group No.: 1649
Filed: 11/26/2003 Examiner: Standley, S.H.
Entitled: Promoter Variants Of The Alpha-7 Nicotinic Acetylcholine Receptor

POWER OF ATTORNEY BY ASSIGNEE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

The United States of America as represented by the Department of Veterans Affairs, as Assignee of record of the entire interest of the above-identified patent application, hereby appoints the members of the firm of MEDLEN & CARROLL, LLP, a firm composed of:

<input checked="" type="checkbox"/> Practitioners associated with Customer Number:	23535
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as attorneys or agents with full power of substitution to prosecute this application and transact all business in the Patent and Trademark Office in connection therewith.

Please direct all future correspondence and telephone calls regarding this application to:

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I hereby certify that the Assignment document filed with the application or filed subsequent to the filing date of the application has been reviewed and I hereby certify that, to the best of my knowledge and belief, title is with The United States of America as represented by the Department of Veterans Affairs.

Dated: DECEMBER 11, 2007

By: 

Name: Deborah K. McCallum

Title: Assistant General Counsel, PSG IV (024)

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PATENT
Attorney Docket No. VARD-07989

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: **Sherry Leonard *et al.***

Serial No.: **10/723,940**

Group No.: **1649**

Filed: **11/26/2003**

Examiner: **Standley, S.H.**

Entitled: **Promoter Variants of the Alpha-7 Nicotinic Acetylcholine Receptor**

**DECLARATION OF INVENTORS
UNDER 37 C.F.R. § 1.132**

MS Amendment

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

COPY

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is being facsimile transmitted to the USPTO or is being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: 10/1/07

By: Cheryl A. Lubet

Dear Examiner Shandley:

We, Sherry Leonard and Robert Freedman, hereby declare and state, under penalty of perjury, that:

1. We are the inventors of the above-named patent application.
2. We have read and understand the specification and claims of the above-named patent application.
3. We are listed as a co-authors on the following publication: Leonard *et al.*, "Association of promoter variants in the alpha7 nicotinic acetylcholine receptor subunit gene with an inhibitory deficit found in schizophrenia," *Arch Gen Psychiatry*, 59:1085-1096, 2002.

4. We confirm that, with respect to the reference listed in paragraph 3, Sherry Leonard and Robert Freedman are the only listed authors who contributed to the inventive process relating to the above named invention.

5. We confirm that, with respect to the reference listed in paragraph 3, that Judith Gault, Jan Hopkins, Judith Logel, Ruby Vianzon, Margaret Short, Carla Drebings, Ralph Berger, Dianna Venn, Pinkhas Sirota, Gary Zerbe, Ann Olincy, Randal Ross and Lawrence Adler were not involved in the inventive process relating to the above named invention. These individuals worked under our supervision and direction, and were listed as co-authors of the publication in order to acknowledge their collaboration in a research program that we direct.

6. We further declare that all statements made herein are of our own knowledge, are true, and that all statements are made on information and belief that are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 Title 18 of the United States Code, and that such willful statements may jeopardize the validity of the application of any patent issued thereon.

Dated: 9-27-07

Sherry Leonard

Sherry Leonard, Ph.D.

Dated: 9/27/07

Robert Freedman

Robert Freedman, M.D.